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*Admitted only in Maryland
*Admitted only in Virginia
*Practice limited to
Federal Agencies

March 18, 2004

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Art Unit 1644

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Application No. 09/357,737; Filed: July 19, 1999
For: **Inducing Cellular Immune Responses to Hepatitis C Virus Using
Peptide and Nucleic Acid Compositions**
Inventors: SETTE *et al.*
Our Ref: 2060.0030005/EKS/PAJ/M-M

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17);
2. Information Disclosure Statement;
3. Form PTO-1449 (26 pages);
4. Copies of 90 documents cited on the Information Disclosure Statement;
5. First Supplemental Information Disclosure Statement;
6. Form PTO-1449 (6 pages);
7. Copies of 25 documents cited on the First Supplemental Information Disclosure Statement;
8. Credit Card Payment Form; and
9. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are

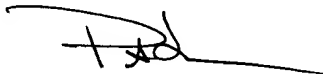
Commissioner for Patents
March 18, 2004
Page 2

necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

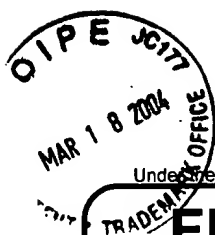
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

PAJ/M-M:amr

242011.1



PTO/SB/17 (10-03)

Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

Application Number	09/357,737
Filing Date	July 19, 1999
First Named Inventor	Alessandro SETTE
Examiner Name	Schwadron, R.B.
Art Unit	1644
Attorney Docket No.	2060.0030005/EKS/PAJ/M-M

METHOD OF PAYMENT (check all that apply)☐ Check ☒ Credit card ☐ Money Order ☒ Other** ☐ None☐ *Charge any deficiencies or credit any overpayments in Deposit Account: the fees to Deposit Acct. No. 19-0036Deposit Account Number: 19-0036
Deposit Account Name: Sterne Kessler, Goldstein & Fox P.L.L.C.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 .80	Provisional filing fee	
SUBTOTAL (1) (\$)			0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	- 20 **=	X	
Multiple Dependent	- 3 **=	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180.00

SUBMITTED BY

Name (Print/Type)	Peter A. Jackman	Registration No. (Attorney/Agent)	45,986	Telephone	(202) 371-2600
Signature		Date	3/14/04		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No.: 09/357,737

Filed: July 19, 1999

For: **Inducing Cellular Immune
Responses to Hepatitis C Virus
Using Peptide and Nucleic Acid
Compositions**

Confirmation No.: 9669

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0030005/EKS/PAJ/M-M

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

In accordance with 37 C.F.R. 1.98(a)(3) and M.P.E.P. § 609(III)(A)(3), Applicants' undersigned representative submits the following with regard to non-English language Document Nos. AM1, AP1, and AN2 cited on form PTO 1449:

Document AM1, Patent No. EP 0 226 513 is in the French language. An English language abstract of document AM1 is attached as Document AS25.

Document AP1, Patent No. WO 92/21033 is in the German language. An English language abstract of document AP1 is located on page one of the document and another English language abstract is attached as Document AT25.

Document AN2, Patent No. WO 94/11738 is in the German language. An English language abstract of document AN2 is located on page one of the document and another English language abstract is attached as Document AR26.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

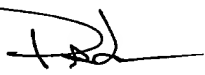
Attached is Form PTO-2038 in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

Date: March 18, 2004

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Washington, D.C. 20005-3934
(202) 371-2600

242051.1



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
2060.0030005/EKS/PAJ/M-MAPPLICATION NO.
09/357,737APPLICANT
SETTE *et al.*FILING DATE
July 19, 1999GROUP
1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	5,200,320	04/06/1993	Sette <i>et al.</i>			12/07/1987
	AB1	5,503,829	04/02/1996	Ladant <i>et al.</i>			11/07/1994
	AC1	5,662,907	09/02/1997	Kubo <i>et al.</i>			01/25/1994
	AD1	6,034,214	03/07/2000	Boon <i>et al.</i>			12/13/1994
	AE						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0 044 710 A1	01/27/1982	Europe			Yes No
	AM1	EP 0 226 513 A1	06/24/1987	Europe			Yes X No
	AN1	WO 92/02543 A1	02/20/1992	WIPO			Yes No
	AO1	WO 92/12996 A2	08/06/1992	WIPO			Yes No
	AP1	WO 92/21033 A1	11/26/1992	WIPO			Yes X No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>1</u>	Aichele, P., <i>et al.</i> , "Antiviral cytotoxic T cell response induced by in vivo priming with a free synthetic peptide," <i>J. Exp. Med.</i> 171:1815-1820, Rockefeller University Press (1990)
	AS	<u>1</u>	Alexander, J., <i>et al.</i> , "Derivation of HLA-A11/K ^b Transgenic Mice. Functional CTL Repertoire and Recognition of Human A11-Restricted CTL Epitopes," <i>J. Immunol.</i> 159:4753-4761, The American Association of Immunologists (November 1997)
	AT	<u>1</u>	Bergmann, C.C., <i>et al.</i> , "Differential Effects of Flanking Residues on Presentation of Epitopes from Chimeric Peptides," <i>J. Virol.</i> 68:5306-5310, American Society for Microbiology (August 1994)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL2	WO 93/03764 A1	03/04/1993	WIPO			Yes No
	AM2	WO 94/03205 A1	02/17/1994	WIPO			Yes No
	AN2	WO 94/11738 A1	05/26/1994	WIPO			Yes X No
	AO2	WO 94/20127 A1	09/15/1994	WIPO			Yes No
	AP2	WO 96/03140 A1	02/08/1996	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Bertoni, R., et al., "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis," <i>J. Clin. Invest.</i> 100:503-513, The American Society for Clinical Investigation, Inc. (August 1997)
	AS	<u>2</u>	Bertoni, R., et al., "Human Class I Supertypes and CTL Repertoires Extend to Chimpanzees," <i>J. Immunol.</i> 161:4447-4455, American Association of Immunologists (October 1998)
	AT	<u>2</u>	Bjorkman, P.J., et al., "Structure of the human class I histocompatibility antigen, HLA-A2," <i>Nature</i> 329:506-512, Macmillan Publishers, Ltd. (1987)

EXAMINER

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 2060.0030005/EKS/PAJ/M-M	APPLICATION NO. 09/357,737
	APPLICANT SETTE et al.	
	FILING DATE July 19, 1999	GROUP 1644

U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>3</u>	Bjorkman, P.J., et al., "The foreign antigen binding site and T cell recognition regions of class I histocompatibility antigens," <i>Nature</i> 329:512-518, Macmillan Publishers, Ltd. (1987)
	AS	<u>3</u>	Buus, S., et al., "Autologous Peptides Constitutively Occupy the Antigen Binding Site on Ia," <i>Science</i> 242:1045-1047, American Association for the Advancement of Science (1988)
	AT	<u>3</u>	Carreno, B.M., et al., "HLA-B37 and HLA-A2.1 molecules bind largely nonoverlapping sets of peptides," <i>Proc. Natl. Acad. Sci. USA</i> 87:3420-3424, National Academy Press (1990)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Corr, M., et al., "Endogenous Peptides of a Soluble Major Histocompatibility Complex Class I Molecule, H-2L ^d : Sequence Motif, Quantitative Binding, and Molecular Modeling of the Complex," <i>J. Exp. Med.</i> 176:1681-1692, Rockefeller University Press (December 1992)
	AS	<u>4</u>	De Bruijn, M.L.H., et al., "Peptide loading of empty major histocompatibility complex molecules on RMA-S cells allows the induction of primary cytotoxic T lymphocyte responses," <i>Eur. J. Immunol.</i> 21:2963-2970, VCH Verlagsgesellschaft mbH (1991)
	AT	<u>4</u>	Del Val, M., et al., "Efficient Processing of an Antigenic Sequence for Presentation by MHC Class I Molecules Depends on Its Neighboring Residues in the Protein," <i>Cell</i> 66:1145-1153, Cell Press (1991)

EXAMINER

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Deres, K., et al., "In vivo priming of virus-specific cytotoxic T lymphocytes with synthetic lipopeptide vaccine," <i>Nature</i> 342:561-564, Macmillan Publishers, Ltd. (1989)
	AS	<u>5</u>	DiBrino, M., et al., "HLA-A1 and HLA-A3 T Cell Epitopes Derived from Influenza Virus Proteins Predicted from Peptide Binding Motifs," <i>J. Immunol.</i> 151:5930-5935, The Association of Immunologists (December 1993)
	AT	<u>5</u>	DiBrino, M., et al., "Endogenous peptides bound to HLA-A3 possess a specific combination of anchor residues that permit identification of potential antigenic peptides," <i>Proc. Natl. Acad. Sci. USA</i> 90:1508-1512, National Academy Press (February 1993)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Ding, Y.-H., <i>et al.</i> , "Two Human T Cell Receptors Bind in a Similar Diagonal Mode to the HLA-A2/Tax Peptide Complex Using Different TCR Amino Acids," <i>Immunity</i> 8:403-11, Cell Press (April 1998)
	AS	<u>6</u>	Eisenlohr, L.C., <i>et al.</i> , "Flanking Sequences Influence the Presentation of an Endogenously Synthesized Peptide to Cytotoxic T Lymphocytes," <i>J. Exp. Med.</i> 175:481-487, The Rockefeller University Press (February 1992)
	AT	<u>6</u>	Engelhard, V.H., "Structure of peptides associated with MHC Class I molecules," <i>Curr. Opin. Immunol.</i> 6:13-23, Current Biology, Ltd. (February 1994)

EXAMINER

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>7</u>	Falk, K., et al., "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules," <i>Nature</i> 351:290-296, Macmillan Publishers, Ltd. (1991)
	AS	<u>7</u>	Falk, K., et al., "MHC peptide motif register. Peptide motifs of HLA-B35 and -B37 molecules," <i>Immunogenetics</i> 38:161-162, Springer-Verlag (April 1993)
	AT	<u>7</u>	Falk, K., et al., "Allele-specific peptide ligand motifs of HLA-C molecules," <i>Proc. Natl. Acad. Sci. USA</i> 90:12005-12009, National Academy Press (December 1993)

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	AR	<u>8</u>	Falk, K., et al., "Pool sequencing of natural HLA-DR, DQ, and DP ligands reveals detailed peptide motifs, constraints of processing, and general rules," <i>Immunogenetics</i> 39:230-242, Springer-Verlag (February 1994)
	AS	<u>8</u>	Falk, K., et al., "Peptide motifs of HLA-A1, -A11, -A31, and -A33 molecules," <i>Immunogenetics</i> 40:238-241, Springer-Verlag (July 1994)
	AT	<u>8</u>	Foon, K.A., "Biological Response Modifiers: The New Immunotherapy," <i>Cancer Res.</i> 49:1621-1639, American Association for Cancer Research (1989)

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	AR	<u>9</u>	Geysen, H.M., et al., "Cognitive Features of Continuous Antigenic Determinants," <i>J. Mol. Recognit.</i> 1:32-41, Heyden & Sons, Ltd. (1988)
	AS	<u>9</u>	Guo, H.-C., et al., "Different length peptides bind to HLA-Aw68 similarly at their ends but bulge out in the middle," <i>Nature</i> 360:364-366, Macmillan Publishers, Ltd. (November 1992)
	AT	<u>9</u>	Henderson, R.A., et al., "HLA-A2.1-Associated Peptides from a Mutant Cell Line: A Second Pathway of Antigen Presentation," <i>Science</i> 255:1264-1266, American Association for the Advancement of Science (March 1992)

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	AR	<u>10</u>	Hill, A., et al., "Characterization of two Epstein-Barr virus epitopes restricted by HLA-B7," <i>Eur. J. Immunol.</i> 25:18-24, VCH Verlagsgesellschaft mbH (January 1995)
	AS	<u>10</u>	Hunt, D.F., et al., "Characterization of Peptides Bound to the Class I MHC Molecule HLA-A2.1 by Mass Spectrometry," <i>Science</i> 255:1261-1263, American Association for the Advancement of Science (March 1992)
	AT	<u>10</u>	Ishioka, G.Y., et al., "Utilization of MHC Class I Transgenic Mice for Development of Minigene DNA Vaccines Encoding Multiple HLA-Restricted CTL Epitopes," <i>J. Immunol.</i> 162:3915-3925, The American Association of Immunologists (April 1999)

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AR	<u>11</u>	Jameson, S.C., and Bevan, M.J., "Dissection of major histocompatibility complex (MHC) and T cell receptor contact residues in a K ^B -restricted ovalbumin peptide and an assessment of the predictive power of MHC-binding motifs," <i>Eur. J. Immunol.</i> 22:2663-2667, VCH Verlagsgesellschaft mbH (October 1992)	
AS	<u>11</u>	Jardetzky, T.S., et al., "Identification of self peptides bound to purified HLA-B27," <i>Nature</i> 353:326-329, Macmillan Publishers, Ltd. (1991)	
AT	<u>11</u>	Kannagi, M., et al., "Target Epitope in the Tax Protein of Human T-Cell Leukemia Virus Type I Recognized by Class I Major Histocompatibility Complex-Restricted Cells," <i>J. Virol.</i> 66:2928-2933, American Society for Microbiology (May 1992)	

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	AR	<u>12</u>	Kast, W.M., et al., "Protection against lethal Sendai virus infection by <i>in vivo</i> priming of virus-specific cytotoxic T lymphocytes with a free synthetic peptide," <i>Proc. Natl. Acad. Sci. USA</i> 88:2283-2287, National Academy Press (1991)
	AS	<u>12</u>	Kast, W.M., et al., "Strict peptide length is not required for the induction of cytotoxic T lymphocyte-mediated antiviral protection by peptide vaccination," <i>Eur. J. Immunol.</i> 23:1189-1192, VCH Verlagsgesellschaft mbH (May 1993)
	AT	<u>12</u>	Krieger, J.I., et al., "Single amino acid changes in DR and antigen define residues critical for peptide-MHC binding and T cell recognition," <i>J. Immunol.</i> 146:2331-2340, American Association of Immunologists (1991)

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	AR	<u>13</u>	Lipford, G.B., et al., "Primary in Vivo Responses to Ovalbumin. Probing the Predictive Value of the K ^b Binding Motif," <i>J. Immunol.</i> 150:1212-1222, The American Association of Immunologists (February 1993)
	AS	<u>13</u>	Maryanski, J.L., et al., "Synthetic peptides as antigens and competitors in recognition by H-2-restricted cytolytic T cells specific for HLA," <i>J. Exp. Med.</i> 167:1391-1405, Rockefeller University Press (1988)
	AT	<u>13</u>	Maryanski, J.L., et al., "Competitor Analogs for Defined T Cell Antigens: Peptides Incorporating a Putative Binding Motif and Polyproline or Polyglycine Spacers," <i>Cell</i> 60:63-72, Cell Press (1990)

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	AR	<u>14</u>	Morrison, J., et al., "Identification of the nonamer peptide from influenza A matrix protein and the role of pockets of HLA-A2 in its recognition by cytotoxic T lymphocytes," <i>Eur. J. Immunol.</i> 22:903-907, VCH Verlagsgesellschaft mbH (April 1992)
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	AT	<u>14</u>	Ochoa-Garay, J., et al., "The ability of peptides to induce cytotoxic T cells <i>in vitro</i> does not strongly correlate with their affinity for the H-2L ^d molecule: implications for vaccine design and immunotherapy," <i>Mol. Immunol.</i> 34:273-281, Elsevier Science, Ltd. (February 1997)

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	AR	<u>15</u>	Pamer, E.G., et al., "Precise prediction of a dominant class I MHC-restricted epitome of <i>Listeria monocytogenes</i> ," <i>Nature</i> 353:852-855, Macmillan Publishers, Ltd. (1991)
	AS	<u>15</u>	Parham, P., et al., "The Origins of HLA-A,B,C Polymorphism," <i>Immunol. Rev.</i> 143:141-180, Munksgaard (February 1995)
	AT	<u>15</u>	Parker, K.C., et al., "Peptide Binding to HLA-A2 and HLA-B27 Isolated from <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 267:5451-5459, American Society for Biochemistry and Molecular Biology, Inc. (March 1992)

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	AO						Yes No
	AP						Yes No

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	AR	<u>16</u>	Parker, K.C., et al., "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2," <i>J. Immunol.</i> 149:3580-3587, American Association of Immunologists (December 1992)
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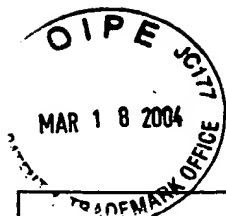
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	AR	<u>17</u>	Reddehase, M.J., et al., "A pentapeptide as minimal antigenic determinant for MHC class I-restricted T lymphocytes," Nature 337:651-653, Macmillan Publishers, Ltd. (1989)
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	AT	<u>17</u>	Rothbard, J.B., "Major histocompatibility complex-peptide interactions," Curr. Opin. Immunol. 2:99-105, Current Biology, Ltd. (1989)

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	AR	<u>18</u>	Röttschke, O., et al., "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T cells," <i>Nature</i> 348:252-254, Macmillan Publishers, Ltd. (1990)
	AS	<u>18</u>	Röttschke, O., et al., "Characterization of Naturally Occurring Minor Histocompatibility Peptides Including H-4 and H-Y," <i>Science</i> 249:283-287, American Association for the Advancement of Science (1990)
	AT	<u>18</u>	Röttschke, O., and Falk, K., "Naturally-occurring peptide antigens derived from the MHC class-I-restricted processing pathway," <i>Immunol. Today</i> 12:447-455, Elsevier Science Publishers, Ltd. (1991)

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	AT	<u>19</u>	Rudinger, J., "Characteristics of the amino acids as components of a peptide hormone sequence," in <i>Peptide Hormones</i> , Parsons, J.A., ed., University Park Press, Baltimore, MD, pp.1-7 (1976)

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	AT	<u>20</u>	Sette, A., et al., "Prediction of major histocompatibility complex binding regions of protein antigens by sequence pattern analysis," Proc. Natl. Acad. Sci. USA 86:3296-3300, National Academy Press (1989)

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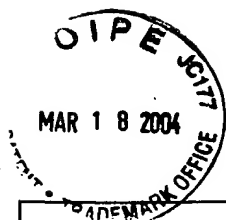
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	AR	<u>21</u>	Sette, A., <i>et al.</i> , "Random association between the peptide repertoire of A2.1 class I and several different DR class II molecules," <i>J. Immunol.</i> 147:3893-3900, The American Association of Immunologists (1991)
	AS	<u>21</u>	Sette, A., <i>et al.</i> , "The Relationship Between Class I Binding Affinity and Immunogenicity of Potential Cytotoxic T Cell Epitopes," <i>J. Immunol.</i> 153:5586-5592, The American Association of Immunologists (December 1994)
	AT	<u>21</u>	Shastri, N., <i>et al.</i> , "Presentation of Endogenous Peptide/MHC Class I Complexes Is Profoundly Influenced by Specific C-Terminal Flanking Residues," <i>J. Immunol.</i> 155: 4339-4346, The American Association of Immunologists (November 1995)

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 2060.0030005/EKS/PAJ/M-M	APPLICATION NO. 09/357,737
	APPLICANT SETTE et al.	
	FILING DATE July 19, 1999	GROUP 1644

U.S. PATENT DOCUMENTS							
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>22</u>	Sherman, L.A., et al., "Extracellular Processing of Peptide Antigens That Bind Class I Major Histocompatibility Molecules," <i>J. Exp. Med.</i> 175:1221-1226, The Rockefeller University Press (May 1992)
	AS	<u>22</u>	Shimojo, N., et al., "Specificity of peptide binding by the HLA-A2.1 molecule," <i>J. Immunol.</i> 143:2939-2947, The American Association of Immunologists (1989)
	AT	<u>22</u>	Sidney, J., et al., "Several HLA Alleles Share Overlapping Peptide Specificities," <i>J. Immunol.</i> 154:247-259, The American Association of Immunologists (January 1995)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>23</u>	Threlkeld, S.C., et al., "Degenerate and Promiscuous Recognition by CTL of Peptides Presented by the MHC Class I A3-like Superfamily. Implications for Vaccine Development," <i>J. Immunol.</i> 159:1648-1657, The American Association of Immunologists (August 1997)
	AS	<u>23</u>	Wentworth, P.A., et al., "Differences and similarities in the A2.1-restricted cytotoxic T cell repertoire in humans and human leukocyte antigen-transgenic mice," <i>Eur. J. Immunol.</i> 26:97-101, VCH Verlagsgesellschaft mbH (January 1996)
	AT	<u>23</u>	Whitton, J.L., et al., "Molecular Analyses of a Five-Amino-Acid Cytotoxic T-Lymphocyte (CTL) Epitope: an Immunodominant Region Which Induces Nonreciprocal CTL Cross-Reactivity," <i>J. Virol.</i> 63:4303-4310, American Society for Microbiology (1989)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>24</u>	Yewdell, J.W., and Bennink, J.R., "Cell Biology of Antigen Processing and Presentation to Major Histocompatibility Complex Class I Molecule-Restricted T Lymphocytes," <i>Adv. Immunol.</i> 52:1-123, Academic Press (July 1992)
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	AT	<u>24</u>	Zhang, Q-J., et al., "An HLA-A11-specific motif in nonamer peptides derived from viral and cellular proteins," <i>Proc. Natl. Acad. Sci. USA</i> 90:2217-2221, National Academy Press (March 1993)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>25</u>	Parker, K.C., et al., "Scheme for Ranking Potential HLA-A2 Binding Peptides Based on Independent Binding of Individual Peptide Side-Chains," <i>J. Immunol.</i> 152:163-175, The American Association of Immunologists (January 1994)
	AS	<u>25</u>	Dialog File 351, Accession No. 7180926, Derwent WPI English language abstract for EP 0 226 513.
	AT	<u>25</u>	Dialog File 351, Accession No. 9263567, Derwent WPI English language abstract for WO 92/21033.

EXAMINER	DATE CONSIDERED
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	26	Dialog File 351, Accession No. 9888606, Derwent WPI English language abstract for WO 94/11738.
	AS		
	AT		

EXAMINER

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



in re application of:

SETTE *et al.*

Appl. No. 09/357,737

Filed: July 19, 1999

For: **Inducing Cellular Immune
Responses to Hepatitis C Virus
Using Peptide and Nucleic Acid
Compositions**

Confirmation No. 9669

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0030005/EKS/PAJ/M-M

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith. A copy of each document is also provided.

Applicants would also like to direct the Examiner's attention to the following co-pending United States Patent Applications which are directed to related technical subject matter:

Application No. 08/205,713, filed March 4, 1994 and submitted herewith as document AS26;

Application No. 08/347,610, filed December 1, 1994 and submitted herewith as document AT26;

Application No. 09/017,524, filed February 3, 1998 and submitted herewith as document AR27; and

Application No. 10/031,345, filed January 18, 2002 and submitted herewith as document AS27.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached with the Information Disclosure Statement filed herewith is PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

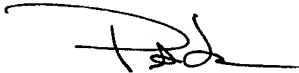
SETTE *et al.*
Appl. No. 09/357,737

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Peter A. Jackman
Attorney for Applicants
Registration No. 45,986

Date: March 18, 2004
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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FORM PTO-1449

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1644**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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	AD						
	AE1	5,662,907	09/02/1997	Kubo <i>et al.</i>			01/25/1994
	AF1	5,932,224	08/03/1999	Chisari			06/06/1995
	AG1	6,037,135	03/14/2000	Kubo <i>et al.</i>			11/29/1993
	AH1	2002/0098197 A1	07/25/2002	Sette <i>et al.</i>			05/30/1995
	AI1	2002/0168374 A1	11/14/2002	Kubo <i>et al.</i>			03/20/1997
	AJ1	2002/0177694 A1	11/28/2002	Sette <i>et al.</i>			02/03/1998
	AK1	2003/0152580 A1	08/14/2003	Sette <i>et al.</i>			11/23/1994

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 01/21189 A1	03/29/2001	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	<u>26</u>	Copy of co-pending U.S. Patent Application No. 08/205,713, Grey <i>et al.</i> , filed March 4, 1994 (NOT PUBLISHED)
	AT	<u>26</u>	Copy of co-pending U.S. Patent Application No. 08/347,610, Kubo <i>et al.</i> , filed December 1, 1994 (NOT PUBLISHED)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>27</u>	Copy of co-pending U.S. Patent Application No. 09/017,524, Kubo <i>et al.</i> , filed February 3, 1998 (NOT PUBLISHED)
	AS	<u>27</u>	Copy of co-pending U.S. Patent Application No. 10/031,345, Sette <i>et al.</i> , filed January 18, 2002 (NOT PUBLISHED)
	AT	<u>27</u>	Battegay, M., <i>et al.</i> , "Patients with chronic hepatitis C have circulating cytotoxic T cells which recognize hepatitis C virus-encoded peptides binding to HLA-A2.1 molecules," <i>J. Virol.</i> 69:2462-2470, American Society for Microbiology (1995)

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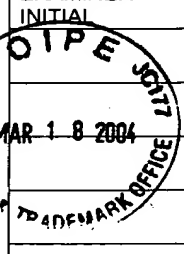
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>28</u>	Bruss, V., "A Short Linear Sequence in the Pre-S Domain of the Large Hepatitis B Virus Envelope Protein Required for Virion Formation," <i>J. Virol.</i> 71:9350-9357, American Society for Microbiology (1997)
AS	<u>28</u>	Chang, K-M., <i>et al.</i> , "Identification of HLA-A3 and -B7-Restricted CTL Response to Hepatitis C Virus in Patients with Acute and Chronic Hepatitis C," <i>J. Immunol.</i> 162:1156-1164, The American Association of Immunologists (January 1999)
AT	<u>28</u>	Diepolder, H.M., <i>et al.</i> , "Immunodominant CD4 ⁺ T-Cell Epitope within Nonstructural Protein 3 in Acute Hepatitis C Virus Infection," <i>J. Virol.</i> 71:6011-6019, American Society for Microbiology (1997)

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	AO						Yes No
	AP						Yes No

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AR	<u>29</u>	Diepolder, H.M., <i>et al.</i> , "The role of hepatitis C virus specific CD4 ⁺ T lymphocytes in acute and chronic hepatitis C," <i>J. Mol. Med.</i> 74:583-588, Elsevier Scientific Publishing Co. (1996)
AS	<u>29</u>	Lamonaca, V., <i>et al.</i> , "Conserved Hepatitis C Virus Sequences Are Highly Immunogenic for CD4 ⁺ T Cells: Implications for Vaccine Development," <i>Hepatology</i> 30:1088-1098, W.B. Saunders Company (October 1999)
AT	<u>29</u>	Preisler-Adams, S., <i>et al.</i> , "Complete nucleotide sequence of a hepatitis B virus subtype adw2, and identification of three types of C open reading frame," <i>Nucleic Acids Res.</i> 21:2258, Oxford University Press (1993)

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	AP						Yes No

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	AR	<u>30</u>	Prezzi, C., <i>et al.</i> , "Virus-specific CD8 ⁺ T cells with type 1 or type 2 cytosine profile are related to different disease activity in chronic hepatitis C virus infection," <i>Eur. J. Immunol.</i> 31:894-906, Wiley-VCH Verlag GmbH (March 2001)
	AS	<u>30</u>	Rehermann, B., <i>et al.</i> , "Cytotoxic T Lymphocyte Responsiveness after Resolution of Chronic Hepatitis GB Virus Infection," <i>J. Clin. Invest.</i> 97:1655-1665, American Society for Clinical Investigation (1996)
	AT	<u>30</u>	Rice, C.M., and Walker, C.M., "Hepatitis C virus-specific T lymphocyte responses," <i>Curr. Opin. Immunol.</i> 7:532-538, Current Biology (1995)

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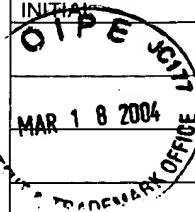
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	AR	<u>31</u>	Rothstein, K.D., and Munoz, S.J., "Interferon and other therapies for hepatitis B and hepatitis C infections," <i>Clin. Lab. Med.</i> 16:465-491, W.B. Saunders (1996)
	AS	<u>31</u>	Scognamiglio, P., <i>et al.</i> , "Presence of Effector CD8 ⁺ T Cells in Hepatitis C Virus-Exposed Healthy Seronegative Donors," <i>J. Immunol.</i> 162:6681-6689, The American Association of Immunologists (June 1999)
	AT	<u>31</u>	Shirai, M., <i>et al.</i> , "Use of intrinsic and extrinsic helper epitopes for <i>in vivo</i> induction of anti-hepatitis C virus cytotoxic T lymphocytes (CTL) with CTL epitope peptide vaccines," <i>J. Infect. Dis.</i> 173:24-31, University of Chicago Press (1996)

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